



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

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RELEASE

Telephone (973) 331-2906

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

REVIEWED BY C.O. DATE

April 2, 1998

WARNING LETTER

Joseph J. DeSantis
President
Great Garlic Foods, Inc.
709 Fifth Avenue
Bradley Beach, NJ 07720

File No: 98-NWJ-20

Dear Mr. DeSantis:

An Investigator from the New Jersey District Office of the Food and Drug Administration conducted an inspection of your garlic manufacturing facility located at 709 Fifth Avenue, Bradley Beach, NJ, on December 22 & 23, 1998. A sample of product labeling was collected for garlic packaged in soybean oil and sold under the product name "Great Garlic."

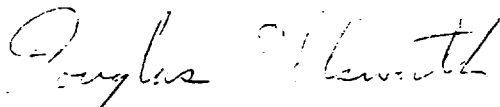
A review of the above garlic product labels revealed that the retail size of this product is misbranded, in that the labels fail to bear nutrition labeling as required under section 403(q)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21 of the Code of Federal Regulations (CFR), Part 101.9. This product does not appear to be eligible for exemption under section 403(q)(5) from this requirement in that your firm manufactures more than 100,000 units of this product annually. In addition, this product has been labeled on or after August 8, 1994.

The above violations are not intended to be an all-inclusive list of labeling deficiencies. It is your responsibility to assure compliance with regulations as required under the Nutrition Labeling and Education Act (NLEA). You should take prompt action to correct these label deficiencies. Failure to promptly correct these violations may result in regulatory action being initiated by the agency without further notice. These actions may include seizure and/or injunction.

You should review labels for all product lines to assure they are in conformance with labeling regulations. For example, if your firm manufactures more than 100,000 units of the product, "Great Garlic chopped in water," annually, its labeling would also have to comply with NLEA requirements. A copy of the FDA's Food Labeling Guide is included with this letter, which should assist you in complying with labeling regulations.

You should notify this office within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations. If corrective actions cannot be accomplished within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Your reply should be sent to the New Jersey District Office, Food and Drug Administration, 10 Waterview Blvd., 3rd Floor, Parsippany, NJ 07054, Attn: William Mestrandrea, Acting Compliance Officer.

Sincerely,



DOUGLAS ELLSWORTH

District Director

New Jersey District

CERTIFIED MAIL-
RETURN RECEIPT REQUESTED

Attachments: FDA Food Labeling Guide